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TITLE: A Treatment Stage Specific Approach to Improving Quality of Life for Women with Ovarian Cancer

PRINCIPAL INVESTIGATOR: Nancy E. Avis, Ph.D.
Brigitte Miller, M.D.

CONTRACTING ORGANIZATION: Wake Forest University
Winston-Salem, NC 27157

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14. ABSTRACT Our primary objective is to identify the issues that are of greatest concern to women in each of three treatment stages: newly diagnosed with ovarian cancer, in-treatment, and post-treatment. A longitudinal, repeated measures design will be used to assess changes in problem areas and quality of life from diagnosis to recurrence among women newly diagnosed with ovarian cancer. The CARES-SF and FACT-O questionnaires will be administered to participants following diagnosis and prior to chemotherapy, during chemotherapy, following chemotherapy, and after recurrence. Data collection for the study will last 28 months (patient accrual will last 25 months and follow-up will continue an additional 3 months). Data for the study will be collected through in-person interviews, and mailed questionnaires (with possible telephone follow-up) from women treated at the Wake Forest University Baptist Medical Center (WFUBMC) and Forsyth Medical Center (FMC).					
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PART I - INTRODUCTION

This study focuses on quality of life among women with ovarian cancer. The primary objective is to identify the issues that are of greatest concern to women in each of three treatment stages: newly diagnosed with ovarian cancer, in-treatment, and post-treatment. A combined cross-sectional and longitudinal, repeated measures design is being used to assess problem areas and quality of life from diagnosis to recurrence among women newly diagnosed with ovarian cancer. The CARES-SF and FACT-O questionnaires are administered to participants following diagnosis and prior to chemotherapy, during chemotherapy, following chemotherapy, and after recurrence.

Data collection for the study will last 28 months (patient accrual will last 25 months and follow-up will continue an additional 3 months). Data for the study are collected through in-person interviews, and mailed questionnaires from women treated at the Wake Forest University Baptist Medical Center (WFUBMC) and Forsyth Medical Center (FMC).

Secondary objectives are of the study: 1) to assess changes in quality of life (as quantified by the FACT-O questionnaire) across the different stages of care, 2) to determine which patient characteristics are predictive of quality of life at each treatment stage, 3) to determine which patient characteristics are predictive of changes in quality of life across the different treatment stages, and 4) to obtain pilot data on problems and quality of life issues for women who experience a recurrence.

PART II – BODY: STATEMENT OF WORK

The primary activities during the first year of the study were to obtain Human Subjects Protection approval from the Department of Defense, finalize study forms, and pilot the study. In August 2002 study recruitment began, but we quickly realized that we needed to change the procedure for questionnaire administration. We realized that instead of having patients complete baseline questionnaires while they were still in the hospital, it would be better to have these questionnaires mailed to patients after their discharge. A request to change the protocol was submitted to HSRRB in September 2002, but we did not receive approval for this change until May 16, 2003. Therefore, much of the time during previous reporting periods was spent waiting for approval from HSRRB for our change in protocol. This delay had a significant impact on our recruitment and ability to conduct the study within the specified timeframe.

During the time we were waiting for the above approval, it also became clear that we needed to add an additional study site. We contacted Forsyth Medical Center (FMC) and they were agreeable to becoming a site. The protocol amendment to request this additional site was submitted to the Office of Human Subjects Protection on 3/14/03, but was not approved until February 2004.

Because we were still concerned about recruiting sufficient numbers of patients to the study, we sought approval to revise our recruitment strategy. We sought to expand the time frame to allow recruitment of women with newly diagnosed ovarian cancer to be recruited up to a month past discharge from the hospital. This request was submitted to the Office of Human Subjects Protection on May 25, 2006 but was not approved until December 28, 2006.

The tasks described in the original statement of work have not changed. However, time involved in obtaining Human Subjects approval from the Department of Defense was not included as part of the original timeline. These approvals have taken an enormous amount of time and have essentially moved the timeline back over almost two years.

Task 1: Develop research protocol (months 1-2)

a. Compile open-ended questions, relevant questionnaires, and sociodemographics in an interview format

The questionnaires have been compiled and approved by the WFUSM and the FMC IRBs.

b. Train study interviewer

The study interviewer has been hired and trained. The project director has also been hired and trained to serve as a back-up interviewer.

c. Pilot test interview with patients

We piloted the interview on 5 participants.

d. Finalize questionnaire based on pilot

The study questionnaire was finalized after the pilot.

Task 2: Develop data management system (months 1-2)

- a. Develop data management requirements
- b. Develop reporting requirements
- c. Develop contact record
- d. Train research staff to use DMS

The above tasks have all been completed.

Task 3: Identify, recruit, and interview patients who meet eligibility criteria (months 3-40)

- a. Identify eligible patients
- b. Recruit and interview patients

To date, 82 patients have been recruited

- c. Conduct quality control of interviews (ongoing)
- d. Develop data entry system

This task has been completed

- e. Transcribe and code open-ended interviews (ongoing)
- f. Abstract clinical data from charts
The abstraction of clinical data is ongoing
- g. Data entry of questionnaires (ongoing)

Task 4: Ongoing Follow-up of Patients (months 6-40)

- a. Track women previously interviewed
- b. Interview women at appropriate treatment stages
- c. Interview recurrent cases

We have begun follow-up of women at appropriate stages. We have not had any recurrent cases. There have been seven participant deaths.

Task 5: Data analysis and report writing (months 41-48)

- a. Transfer data into SAS
- b. Clean data and generate codebooks
- c. Analyze data from interviews
- d. Present results at professional meeting
- e. Prepare initial manuscripts

Task 5 has not yet begun

Task 6: Develop interventions that can be tested in future research (month 36)

- a. Review findings and develop ideas for interventions
- b. Plan interventions for future trials

Task 6 has not yet begun

PART III - KEY RESEARCH ACCOMPLISHMENTS

- Finalization of study forms
- Obtaining human subjects protection approval
- Recruitment of an additional study site

PART IV - REPORTABLE OUTCOMES

None

PART V - CONCLUSIONS

This section is not applicable at this point.

PART VI - REFERENCES

Not applicable